To: Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]
From: noreply+feedproxy@google.com
Sent: Fri 1/31/2014 7:12:03 AM
Subject: Should we be holding our breath waiting for more information on risks of the chemical spilled in West Virginia?

Should we be holding our breath waiting for more information on risks of the chemical spilled in West Virginia?

Should we be holding our breath waiting for more information on risks of the chemical spilled in West Virginia?

Posted: 30 Jan 2014 02:38 PM PST

By Richard Denison

***Richard Denison, Ph.D.*, is a Senior Scientist.**

A hearing held yesterday by the West Virginia Legislature's Joint Legislative Oversight Commission on State Water Resources created quite a stir, when a witness – West Virginia Environmental Quality Board vice-chairman Scott Simonton – said that the human carcinogen formaldehyde had been detected in several water samples drawn from a Charleston, WV, restaurant, and that people in the area affected by the January 9 spill could be expected to have inhaled the chemical, which he identified as a likely breakdown product of the spilled material, crude MCHM. See stories in the *Charleston Gazette* and *USA Today*.

State officials and the West Virginia American Water company were quick to call Simonton's claims "unfounded" and "misleading and irresponsible," respectively. The controversy led even the American Chemistry Council – which has laid low ever since the spill – to quickly issue its first statement related to the spill through its Formaldehyde Panel.

While experts are noting that data are insufficient to identify the spill as the source of any formaldehyde detected in the water samples, this new kerfuffle does point to yet another major data gap on crude MCHM.

The one part-per-million (1 ppm) "safe" level state and federal officials set was based on limited data from studies in which rats were exposed to crude or pure MCHM through *oral ingestion*. Absolutely no data are available on the chemical with respect to exposure through *inhalation*. Yet officials did not hesitate to tell residents the 1 ppm level would be safe not only for drinking the water, but also for bathing and showering.

(It's curious that the Eastman Chemical Company apparently performed no inhalation studies on crude or pure MCHM, given that Eastman said its motivation for the studies it did perform was to understand risks to workers in industrial settings, and its safety data sheet for crude MCHM prominently notes the potential for health concerns for workers from inhalation.)

Clearly the material that spilled is volatile – that's why people can smell it. Taking a hot shower in such water means that people would clearly be exposed via inhalation of the vapor; how much exposure would occur has not been ascertained. But in the absence of any data as to toxicity of the chemical via inhalation, there is simply no scientific basis on which to say or imply that showering in water contaminated at 1 ppm level was OK.

Chemicals can be more or less toxic by inhalation than by ingestion, with one study finding inhalation to be the

more toxic route for half of the chemicals examined and oral ingestion to be the more toxic route for the other half. Benzene, for example, is estimated to be several hundred times more toxic by inhalation than by ingestion, while inhalation of chloroform is estimated to be about 25-fold lower in toxicity than it is by ingestion.

What such comparisons indicate is that extrapolating from data on oral toxicity to predict inhalation toxicity – which is effectively what government officials did in this case – is about as accurate as flipping a coin..

Getting the data on chemicals is just the beginning

Posted: 30 Jan 2014 10:19 AM PST

By Jennifer McPartland

Jennifer McPartland, Ph.D., is a Health Scientist.

Common sense tells us it's impossible to evaluate the safety of a chemical without any data. We've repeatedly highlighted the scarcity of information available on the safety of chemicals found all around us (see for example, here and here). Much of this problem can be attributed to our broken chemicals law, the Toxic Substances Control Act of 1976 (TSCA).

But even for those chemicals that have been studied, sometimes for decades, like formaldehyde and phthalates, debate persists about what the scientific data tell us about their specific hazards and risks. Obtaining data on a chemical is clearly a necessary step for its evaluation, but interpreting and drawing conclusions from the data are equally critical steps – and arguably even more complicated and controversial.

How should we evaluate the quality of data in a study? How should we compare data from one study relative to other studies? How should we handle discordant results across similar studies? How should we integrate data across different study designs (e.g., a human epidemiological study and a fruit fly study)? These are just a few examples of key questions that must be grappled with when determining the toxicity or risks of a chemical. And they lie at the heart of the controversy and criticism surrounding chemical assessment programs such as EPA's Integrated Risk Information System (IRIS).

Recently, a number of efforts have been made to *systematize* the process of study evaluation, with the goal of creating a standardized approach for unbiased and objective identification, evaluation, and integration of available data on a chemical. These approaches go by the name of systematic review.

Groups like the National Toxicology Program's Office of Health Assessment and Translation (OHAT) and the UCSF-led Navigation Guide collaboration have been working to adapt systematic review methodologies from the medical field for application to environmental chemicals. IRIS has also begun an effort to integrate systematic review into its human health assessments.

Recently a paper in Environmental Health Perspectives (EHP) by Krauth et al. systematically identified and reviewed tools currently in use to evaluate the quality of toxicology studies conducted in laboratory animals. The authors found significant variability across the tools; this finding has significant consequences when reviewing the evidence for chemical hazard or risk, as we pointed out in our subsequent commentary ("A Valuable Contribution toward Adopting Systematic Review in Environmental Health," Dec 2013).

EDF applauds these and other efforts to adopt systematic review in the evaluation of chemical safety. Further elaboration of EDF's perspective on systematic review can be found here.